

# A trial of withdrawal of nocturnal non-invasive positive pressure ventilation (NIPPV) in chronic obstructive pulmonary disease (COPD) patients with chronic hypercapnic ventilatory failure previously stable on nocturnal NIPPV

<b>Submission date</b> 23/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Nick Oscroft

**Contact details**  
Papworth Hospital NHS Trust  
Papworth Everard  
Cambridge  
United Kingdom  
CB3 8RE  
+44 (0)1480 830541

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

04/Q0104/139 - NRR Publication ID: N0542155456

# Study information

## Scientific Title

### Study objectives

Currently it is unclear whether patients with severe COPD benefit from noninvasive positive pressure ventilation in the long term. There is divided opinion and evidence on whether this is a beneficial treatment and who might benefit. In performing this clinical trial of withdrawal of a non-proven treatment with close monitoring we plan to address the issue of whether or not the treatment does maintain the patients in a stable clinical state and improve their quality of life.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Treatment

## Participant information sheet

### Health condition(s) or problem(s) studied

Chronic Obstructive Pulmonary Disease (COPD)

### Interventions

Comparison of withdrawing long term NIPPV treatment or continuing

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

'Withdrawal Failure' as stipulated by preset criteria. The effect of withdrawal of NIPPV therapy on arterial blood gas analysis.

Criteria for Withdrawal Failure:

1. Daytime PaCO<sub>2</sub> >9 kPa
2. Nocturnal PtcCO<sub>2</sub> >10 on night study
3. Respiratory acidosis pH <7.35
4. Intolerable symptoms, including morning headache and drowsiness

**Secondary outcome measures**

1. Assess the effect of withdrawal of NIPPV therapy on: quality of life using SF-36 and St George's respiratory questionnaire, exacerbation rates, hospital admissions, GP contact and requirements for treatment with antibiotics and steroids
2. Assess that if preset criteria are met, reinstitution of NIPPV therapy has positive effects
3. Measure changes to spirometric, mouth pressure data and exercise capacity

**Overall study start date**

16/05/2005

**Completion date**

31/01/2007

**Eligibility****Key inclusion criteria**

Pre-screening criteria:

1. Diagnosis of COPD: forced expiratory volume in 1 second (FEV<sub>1</sub>) <50% predicted, FEV<sub>1</sub>/forced vital capacity (FVC) ratio <70%, total lung capacity (TLC) >80% predicted
2. Smoking history >20 pack years
3. Prior to commencing NIPPV hypercapnic ventilatory failure with daytime PaCO<sub>2</sub> >7.5 kPa with normal pH (7.35-7.45) or nocturnal PtcCO<sub>2</sub> >9 kPa
4. On NIPPV for at least 3 months with compliance of >4 hours/day
5. Live within 40-mile radius of trust

Screening criteria:

1. Clinically stable - no increase in breathlessness, cough or sputum volume in 4 weeks between initial assessment and entry to trial
2. PaCO<sub>2</sub> within +/-1 kPa of initial assessment
3. No change in spirometry (<15% or 200 ml) from initial assessment

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Age over 80
2. Other significant respiratory disease (interstitial lung disease, asthma, bronchiectasis, neuromuscular or restrictive chest wall disorders)
3. Significant documented left ventricular dysfunction with Ejection Fraction <40%
4. Obstructive sleep apnoea with an apnoea/hypopnoea index of over 10, which is reversible by continuous positive airway pressure (CPAP)

**Date of first enrolment**

16/05/2005

**Date of final enrolment**

31/01/2007

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

Papworth Hospital NHS Trust

Cambridge

United Kingdom

CB3 8RE

**Sponsor information****Organisation**

Papworth Hospital NHS Trust (UK)

**Sponsor details**

Papworth Everard

Cambridge

England

United Kingdom

CB3 8RE

+44 (0)1480 830541

diane.bilton@papworth.nhs.uk

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01qbebb31>

## Funder(s)

**Funder type**

Industry

**Funder Name**

Respiratory Support and Sleep Centre Trust fund supported by an unrestricted grant from B & D Electromedical (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2010		Yes	No